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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,724	09/26/2003	Kelvin G.M. Brockbank	113024	6643

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,724	BROCKBANK ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *3 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-29 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/31/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35 are pending. Claims 1, 2, 4-29, 31-35 are considered on the merits to the extent they read on the elected species, "cell culture" and "trehalose". Claims 3 and 30 are withdrawn from consideration as being drawn to a non-elected species.

Election/Restriction

Applicant's election with traverse of species "cell culture" and "trehalose" in the reply filed on 2/10/06 is acknowledged. The traversal is on the ground that examination of all species would not be burdensome. This is not found persuasive because the searches are not coextensive, especially with regard to the literature searches performed by text searching. If applicant will admit on the record that all species are obvious variants of one another, and that a reference with renders one species anticipated or obvious will be accepted as rendering all species anticipated or obvious, the requirement for election of species may be withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 1 is objected to because of the following informalities: Method claims should be in active language, claim 1, line 2 should be "incubating the material".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-6, 8-29, 31-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gilles *et al.* [U].

The claims are directed to a method of preserving living cellular material comprising: incubating the material in a culture medium containing at least one sugar for at least three hours and preserving.

Gilles *et al.* disclose a method comprising : incubating L929 cells in culture medium containing 0.3M sucrose for the time it takes for 10 passages, adding trehalose to the medium prior to freezing and drying.

Claims 1, 2, 4-11, 15-20, 23-29, 31-33 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 6,770,478 [A].

US 6,770,478 disclose, in examples 7-9, a method of incubating a cell in culture medium with 90mM trehalose for 24 hours. The cells are then harvested and resuspended in 150mM trehalose, frozen and dried.

Claims 28, 29, 31-32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Scannell *et al.* [V].

Scannell *et al.* disclose a method comprising incubating cells for 10 days (240 hours) in 5mM trehalose.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-14, 17-29, 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim *et al.* [W].

The claims are directed to a method of preserving living cellular material comprising: incubating the material in a culture medium containing at least one sugar for at least three hours and preserving. The elected species are cell culture and trehalose.

Kim *et al.* disclose a method comprising incubating a cell culture of *T. chinensis* in a culture medium comprising 1M trehalose for 30 mins and freezing (Table 4). The reference lacks the incubation with trehalose for at least three hours.

It would have been obvious to incubate the cell culture for three hours or longer because an incubation of 30 minutes with trehalose is shown to increase viability. One of skill in the art may increase the incubation time in the absence of evidence of criticality. Further, the differences in the concentration of trehalose is also considered to be an element of experimental design, particularly because 1M trehalose used in the prior art is in within the range of claim 26. See MPEP 2144.05.

Claims 1, 2, 4-29, 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilles *et al.* [V].

The claims and the reference have been discussed above.

Gilles *et al.* lack the disclosure of an incubation duration of 3-120 hours. Gilles *et al.* disclose that the duration of incubation is for 10 passages, while the length of time necessary for one passage of L929 cells is not specifically disclosed, it is assumed to be a least 24 hours. However, the length of time of incubation is considered to be an element of experimental design in the absence of any criticality.

Claims 1, 2, 4-29, 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,770,478 [A].

US 6,770,478 discloses a method of cell preservation where cells are incubated in a medium containing a concentration of trehalose in the loading (cryopreservation) medium from about 10mM to about 1.5M (col. 18, l. 60). The duration of the incubation is preferably about 4-24 hours (col. 19, l. 58). The internal concentration to be achieved is any suitable amount, preferably about 10mM-90mM trehalose (col. 19, l. 9). In examples 7-9, a method of incubating a cell in culture medium with 90mM trehalose for 24 hours. The cells are then harvested and resuspended in 150mM trehalose, frozen and dried.

Regarding claims 12-14, the duration of incubation is considered to be an element of experimental design in the absence of evidence of criticality. The reference teaches the preferable range of about 4-24 hours. However, one of skill in the art may choose any length of incubation time in the absence of criticality.

Claims 1, 2, 4-29, 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 20050277107 [B] in combination with US 6,770,478 [A].

US 20050277107 disclose a cell preservation method. The cells are prepared by inserting carbohydrates...or by exposing the cell to the carbohydrates...[0057]. The intracellular concentration may be about 0.01 to 1M of carbohydrate such as trehalose [0069]. The carbohydrate may be delivered by any suitable non-lethal intracellular deliver technique [0065]. Many preservation methods are contemplated.

Specifically exemplified is suspending cultured fibroblast cells in RPMI-1640 with 0.2M trehalose for 45 minutes in the presence of a pore forming compound (example 1). The cells are then placed in an isotonic trehalose solution (0.2M) and dried (Examples 2, 3).

The reference lacks the specific disclosure of incubating the cells for greater than 3 hours.

US 6,770,478 has been described above.

The substitution of the incubation method taught in US 6,770,478 in the method of US 20050277107 for loading cells would have been obvious because US 20050277107 teaches that any method may be used for carbohydrate loading and teaches intracellular concentrations to be achieved for efficient dry preservation. Therefore, one of skill in the art may use a known method of carbohydrate incorporation, that is incubation with the carbohydrate for any period of time necessary to provide sufficient intracellular concentrations of carbohydrate such as trehalose.

Claims 28, 29, 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scannell *et al.* [V].

The claims are further directed to a length of incubation of 3-120 hours and use of 0.1-0.3M polysaccharide.

Scannell *et al.* disclose that the length of incubation is 10 days (240 hours) and the concentration of trehalose in the incubation medium is 5mM. The reference lacks the disclosure of a maximum incubation time of 120 hours and the use of greater than 5mM trehalose in the medium.

Changes in concentration and duration of incubation are considered to be elements of experimental design in the absence of evidence of criticality. One of skill in the art may increase a concentration and decrease a duration as these parameters are considered to be elements of experimental design, MPEP 2144.05.

Claims 28, 29, 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burger *et al.* [X].

Burger *et al.* disclose a method of incubating cells in a culture media comprising 5% trehalose for 30, 60 and 90 mins., Tables 2 and 6 and Fig 9.

Burger *et al.* do not exemplify incubating for at least 3 hours.

Changes in duration of incubation are considered to be elements of experimental design in the absence of evidence to the contrary.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
March 14, 2006